

REMARKS

With this response, claims 1-34 are pending and under consideration to the extent they read on the elected species. Claims 1, 4-6, 8, 9, 12-21, and 23-25 have been amended, and no claims have been canceled or added. As such, claims 1-34 remain pending and under consideration to the extent they read on the elected species. Support for the amendments may be found in the specification, *e.g.*, at para. [0264] and elsewhere. As such, no new matter enters by way of the present amendment. Entry of the amendment and reconsideration of the application as amended is respectfully requested.

Allowable Subject Matter

The Examiner is thanked for the indication that method claims are allowable to the extent they read on the elected species.

Finality of Rejection

As an initial matter, Applicants respectfully request withdrawal of the finality of the present Office Action as premature. Pursuant to M.P.E.P. § 706.07(a), an action on the merits is not properly made final when the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed under defined circumstances. In the present case, the rejection under 35 U.S.C. § 112, first paragraph is present for the first time in Final Office Action, and was not necessitated by Applicants amendment nor based on information submitted in an information disclosure statement. As such, it is submitted that the finality of the present Office Action is premature, and withdrawal of the finality of the Office Action is respectfully requested. Entry of the present amendment and reconsideration of the application as amendment and following remarks is requested.

Rejection of Claims under 35 U.S.C. §112, First Paragraph

Claims 1-13 stand rejected under 35 U.S.C. §112, First Paragraph as allegedly failing to comply with the written description requirement. Applicants respectfully traverse for at least the reasons which follow.

The standard for determining whether a claim drawn to a genus meets the written description requirement is clear. “The written description requirement for a claimed genus may

be satisfied through sufficient description of a representative number of species, by actual reduction to practice . . . , reduction to drawings . . . , or by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.” See *Regents of the University of California v. Eli Lilly*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406; M.P.E.P. § 2163(II)(3)(a)(ii) (emphasis added). Applicants have met this burden.

Initially, it is noted that the present claims are not drawn to a new genus of compounds, but rather to new uses of a generally known class of compounds. Nonetheless, what constitutes a “representative number” of species is an inverse function of the skill and knowledge in the art. *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005). Satisfactory disclosure of a “representative number” depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. Description of a representative number of species does not require the description to be of such specifics that it would provide individual support for each species that the genus embraces. “That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation.” *Falkner v. Inglis*, 448 F.3d, 1357, 1366 (Fed Cir. 2006). Also relevant to the analysis is the claimed invention, and the context of the genus within the claimed invention.

In this regard, the present claims at issue are directed to various methods for increasing urine flow, decreasing the concentration of potassium in urine, alleviating a condition or disorder associated with toxic hypervolemia, or treating congestive heart failure in an individual in need thereof by administering GLP-1 or a GLP-1 agonist analog or derivative. Thus, the scope of the genus of GLP-1 compounds is viewed in the context of the claimed method, and the disclosure

of species within the genus is understood by those skilled in the art based on the scope of teachings related to the claimed methods.

Within this context, any suitable GLP-1 molecule or agonist thereof may be useful in the claimed methods, *e.g.*, useful for increasing urine flow, decreasing the concentration of potassium in urine, alleviating a condition or disorder associated with toxic hypervolemia, or treating congestive heart failure. Moreover, in order to facilitate prosecution, the claims have been amended to further clarify that the GLP-1 agonist is an analog or derivative. In this regard, the specification provides detailed guidance as to methodologies for preparing screening for GLP-1 agonists which retain suitable activity in the context of the methods of the present claims (see, *e.g.*, paras. [0264], [0258]-[0267]). Moreover, extensive exemplary embodiments of known GLP-1 agonists with suitable activity in the context of the present claims are discussed in the specification. See, *e.g.*, paras. [0191]-[0230]. In this regard, it is noted that such GLP-1 peptide molecules and peptide agonists thereof were generally known at the time of filing, as recognized by those skilled in the art. For instance, see, *e.g.*, U.S. 5,512,549; 5,574,008; 5,545,618; 5,118,666; 5,120,712, etc. (as cited in the present specification at para. [0191]).

It is now well-established that the binding precedent of the Federal Circuit “does *not* set forth a *per se* rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art.” *Falkner* at 1367 (emphasis in original). Indeed the Federal Circuit has held that requiring patentees to recite known sequences would serve no goal of the written description requirement. *Id.* at 1368. Nonetheless, the specification provides extensive disclosure, embodiments, and guidance with regard to GLP-1 peptide molecules and peptide agonists thereof, including numerous examples and methods for identifying compounds useful within the context of the claimed methods.

Applicants respectfully submit that one skilled in the art would readily appreciate that Applicants, at the time of the filing of the present application, were in possession of the methods of the claimed invention, including the recited genus of compounds and scope of methods and, therefore, have met the written description requirement. As such, it is submitted that the claims comply with 35 U.S.C. §112, first paragraph, and reversal of this rejection is respectfully requested.

Double Patenting Rejection

Claims 1-13 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-34 of U.S. Patent No. 6,703,359. Applicants respectfully traverse. By way of election requirement during prosecution of the application leading to U.S. Patent No. 6,703,359, the Examiner required election between exendin-related sequences and GLP-1-related sequences. In response, Applicants elected the exendin-related sequences for prosecution, and the present application was filed as a divisional application.

As such, Applicants submit that there is no proper basis for an obviousness-type double patenting rejection based on an Patent from which the present application claims benefit as a divisional application, given that the rejected claims are within the election requirement. Withdrawal of this rejection is therefore respectfully requested.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned at (303) 863-2303 should any additional information be necessary for allowance.

Respectfully submitted,

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